

P#3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and  
Scott Siegel

Application No.: 10/043,436 Group Art Unit: 1644

Filed: January 20, 2002 Examiner: Not Assigned

Confirmation No.: 3843

Title: METHODS OF TREATING HEPATITIS WITH CHIMERIC ANTI-TNF  
ANTIBODIES



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SEP 30 2002

TECH CENTER 1600/2900

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>9-19-02</u>	Signature <u>Linda M. Amato</u>
_____ Linda M. Amato _____ Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

Copies of the cited references are enclosed.

Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. 09/927,703, U.S. Application No: 09/756,398 and U.S. Application No: 09/133,119 to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.

Some of the listed references were cited in the enclosed International Search Report and European Search Report in a counterpart foreign application. [ISR References AS, AV, AU, AZ, AX7, AY7 and AZ7; ESR References AP2, AM3, AN3, AO3, AP3, AQ3 and AL5]

The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- the explanation provided on the attached sheet.
- the explanation provided in the Specification.
- submission of the enclosed International Search Report.
- the enclosed English language abstract.

Applicant requests that the following pending applications be considered:

Examiner's  
Initials

U.S. Patent Application No. 09/756,398, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-006

U.S. Patent Application No. 09/756,301, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-008

U.S. Patent Application No. 09/766,535, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 18, 2001, Docket No.: 0975.1005-010

U.S. Patent Application No. 09/897,724, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 2, 2001, Docket No.: 0975.1005-012

U.S. Patent Application No. 09/927,703, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed August 10, 2001, Docket No.: 0975.1005-013

U.S. Patent Application No. 10/010,229, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed December 7, 2001, Docket No.: 0975.1005-014

U.S. Patent Application No. 10/043,450, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-015

U.S. Patent Application No. 10/044,534, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-016

U.S. Patent Application No. 10/043,432, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-017

U.S. Patent Application No. 10/176,460, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 20, 2002, Docket No.: 0975.1005-019

U.S. Patent Application No. 10/187,121, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 28, 2002, Docket No.: 0975.1005-020

U.S. Patent Application No. 10/186,559, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed June 28, 2002, Docket No.: 0975.1005-021

U.S. Patent Application No. 10/198,845, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 18, 2002, Docket No.: 0975.1005-022

U.S. Patent Application No. 10/200,795, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 22, 2002, Docket No.: 0975.1005-023

U.S. Patent Application No. 10/208,195, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 29, 2002, Docket No.: 0975.1005-024

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Examiner

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Date

The specification for the above cited co-pending applications is identical to the present specification (10/043,436). Therefore, only a copy of the current claims for each application is enclosed. Copies of the specifications of the co-pending applications will be provided upon request.

A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

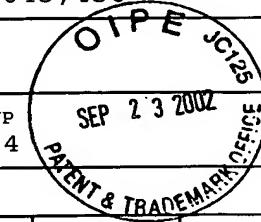
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Dated: September 19, 2002

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0975.1005-018	APPLICATION NO. 10/043,436
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		APPLICANT Junming Le et al.	
September 19, 2002 (Use several sheets if necessary)		FILING DATE January 10, 2002	GROUP 1644



## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,603,106	07/29/86	Cerami et al.	435	7	
	AB	4,822,776	04/18/89	Cerami et al.	514	21	
	AC	5,658,570	08/19/97	Newman et al.	424	184.1	
	AD	5,750,105	5/12/98	Newman et al.	424	133.1	
	AE	5,231,024	7/27/93	Moeller et al.	435	240.27	
	AF	5,223,395	06/29/93	Gero	435	71	
	AG	5,436,154	07/25/95	Barbanti et al.	435	240.27	
	AH	5,654,407	08/05/97	Boyle et al.	530	388.15	
	AI	5,700,788	12/23/97	Mongelli et al.	514	91	
	AJ	5,730,975	03/24/98	Hotamisligil et al.	424	130.1	
	AK	5,741,488	04/21/98	Feldman et al.	424	154.1	

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	AN	0 288 088 A2	26 OCT 88	EPO			
	AO	0 308 378 A2	22 MAR 89	EPO			
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	AQ	0 393 438 A3	24 OCT 90	EPO			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).
AS	Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985).
AT	Morrison, Sherie L., "Transfectedomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).

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INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION  
September 19, 2002  
(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
0975.1005-018APPLICATION NO.  
10/043,466APPLICANT  
Junming Le et al.FILING DATE  
January 10, 2002GROUP  
1644

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	AA2	5,776,947	07/07/98	Kroemer et al.	514	312	SEP 3 0 2002
	AB2	6,015,558	01/18/00	Hotamisligil et al.	424	142.1	
	AC2	6,172,202 B1	01/09/01	Marcucci et al.	530	406	
	AD2	6,194,451 B1	02/27/01	Alpegiani et al.	514	459	

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	AL2	0 398 327 A1	22 NOV 90	EPO			
	AM2	0 412 486 A1	13 FEB 91	EPO			
	AN2	0 433 900 A1	26 JUN 91	EPO	-		
	AO2	0 526 905 A2	10 FEB 93	EPO			
	AP2	WO91/02078	21 FEB 91	PCT			
	AQ2	WO92/07076	30 APR 92	PCT			

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AU	Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. &amp; Biophys. Res. Comm.</i> , 137(2):847-854 (1986).
AV	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).
AW	Piguet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," <i>J. Exp. Med.</i> , 166:1280-1289 (1987).
AX	Meager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).
AY	Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION			APPLICANT Junming Le et al.	O I P E JC125 SEP 23 2002 PATENT & TRADEMARK OFFICE
September 19, 2002 (Use several sheets if necessary)			FILING DATE January 10, 2002	

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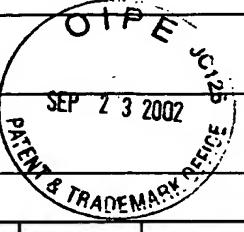
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AL3		WO 92/13095	06 AUG 92	PCT			RECEIVED
AM3		0 260 610 A2	23 MAR 88	EPO			SEP 30 2002
AN3		91/09967	11 JUL 91	PCT			TECH CENTER 1600/2900
A03		0 351 789 A2	24 JAN 90	EPO			
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AL4		WO 92/11383	09 JUL 92	PCT			
AM4		WO 93/02108	04 FEB 93	PCT			
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AR2	Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).
AS2	Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).
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AU2	Di Giovine, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," <i>Annals of the Rheumatic Diseases</i> , 47:768-772 (1988).
AV2	Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting</i> 1989.

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PTO-1449 REPRODUCED <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> September 19, 2002 (Use several sheets if necessary)			ATTORNEY DOCKET NO. 0975.1005-018		APPLICATION NO. 10/043,436		
			APPLICANT Junming Le et al.				
			FILING DATE January 10, 2002		GROUP 1644		
							
<b>U.S. PATENT DOCUMENTS</b>							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
AO4		WO 91/09967	11 JUL 91	PCT			<b>RECEIVED</b>
AP4		0 486 526 B2	07 MAR 01	EPO			SEP 30 2002
AQ4		WO 92/02190	10 JUN 92	PCT			
AL5		0 288 088 B1	26 OCT 88	EPO			TECH CENTER 1600/2900
AM5		0 351 789 B1	24 JAN 90	EPO			
AN5		0 453 898 A2	30 OCT 91	EPO			X
AO5		0 585 705 A1	09 MAR 94	EPO			
AP5		0 614 984 A2	14 SEP 94	EPO			
AQ5		0 663 836 B1	26 JUL 95	EPO			
AL6		WO 89/08460	21 SEP 89	PCT			
AM6		WO 90/01950	08 MAR 90	PCT			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
AW2	Exley, A.R. et al., "Monoclonal Antibody (Mab) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," <i>Medical Research Society, Abstract 184</i> , p. 50 (1989).						
AX2	Cross, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor $\alpha$ /Cachectin and Murine Interleukin 1 $\alpha$ Protects Mice from Lethal Bacterial Infection," <i>J of Exp Med.</i> , 169:2021-2027 (1989).						
AY2	Engelmann, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," <i>J. of Bio. Chem.</i> , 264(20):11974-11980 (1989).						
EXAMINER			DATE CONSIDERED				

PTO-1449 REPRODUCED			ATTORNEY DOCKET NO. 0975.1005-018	APPLICATION NO. 10/043,436
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			APPLICANT Junming Le et al.	GROUP 1644
September 19, 2002  (Use several sheets if necessary)			FILING DATE January 10, 2002	



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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AN6	WO 91/04054	04 APR 91	PCT			RECEIVED
	AO6	WO 92/01472	06 FEB 92	PCT			SEP 30 2002
	AP6	WO 93/11236	10 JUN 93	PCT			TECH CENTER 1600/2900
	AQ6	WO 94/08609	28 APR 94	PCT			
	AL7	WO 94/08619	28 APR 94	PCT			

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AR3	Fong, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 $\beta$ and Interleukin 6 Appearance During Lethal Bacteremia," <i>J. Exp. Med.</i> , 170:1627-1633 (1989).
AS3	Von Asmuth, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF- $\alpha$ ) and Interleukin 6 in a Zymosan-Induced Shock Model," <i>Scand. J. Immunol.</i> , 32:313-319 (1990).
AT3	Herve, P. et al., "Monoclonal Anti TNF $\alpha$ Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).
AU3	Silva, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- $\alpha$ in Experimental Gram-Negative Shock," <i>J. of Infectious Diseases</i> , 162:421-427 (1990).
AV3	Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990).
AW3	Tavernier, Jan et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis," <i>J. Mol. Biol.</i> , 211:493-501 (1990).
AX3	Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- $\alpha$ monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).
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PTO-1449 REPRODUCED			ATTORNEY DOCKET NO. 0975.1005-018	APPLICATION NO. 10/043,436
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			APPLICANT Junming Le et al.	C-125 O P E SEP 23 2002 PATENT & TRADEMARK OFFICE TECH CENTER 1600/2900
September 19, 2002 (Use several sheets if necessary)			FILING DATE January 10, 2002	

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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

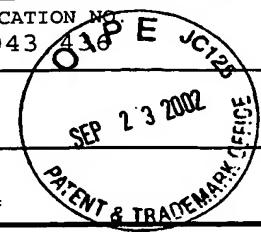
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AZ3	Nophar, Yaron et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," <i>The EMBO Journal</i> , 9(10):3269-3278 (1990).
AR4	Engelmann, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).
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AT4	Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).
AU4	Schall, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).
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AW4	Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).
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AY4	Ruddle, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," <i>J. Exp. Med.</i> , 172:1193-1200 (1990).

EXAMINER

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PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  September 19, 2002  (Use several sheets if necessary)		ATTORNEY DOCKET NO. 0975.1005-018	APPLICATION NO. 10/043 436 O P E SC128	
		APPLICANT Junming Le et al.	FILING DATE January 10, 2002	GROUP 1644



## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AZ4	Galloway, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," <i>J. of Immunological Methods</i> , 140:37-43 (1991).
AR5	Waldmann, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," <i>Science</i> , 252:1657-1662 (1991).
AS5	Aderka, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," <i>Israel J. Med. Sci.</i> , 28(2):126-130 (1992).
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AX5	Beutler, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," <i>J. Exp. Med.</i> , 161:984-995 (1985).
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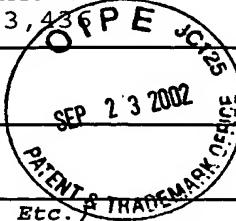
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